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19.03.09 corr. (IDS)
Deadline: 19.05.09 corr. 9

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20. Jan. 2009
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Application No.	Ref.	Date
03 740 370.6 - 2320	INO10504PCTEP	19.01.2009
Applicant: INO Therapeutics GmbH		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

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Borowski, Aleksander
Primary Examiner
For the Examining Division

Enclosure(s): 3 page/s reasons (Form 2906)
US5320093, XP002283209

The examination is being carried out on the **following application documents**:

Description, Pages
1-10 as published

Claims, Numbers
1-6 received on 14.03.2005 with letter of 14.03.2005

Drawings, Sheets
1/2, 2/2 as published

1. This communication has been issued in the response to the applicant's letter dated 22.12.2008 sent in preparation to the oral proceedings (cancelled) on 26.01.2009. The applicant's observations filed with said letter have been carefully considered.

2. The Examining Division agrees with the applicant's argumentation with respect to document D1 in that said document does not unambiguously teach about the administration of carbon monoxide.

3. The following documents (D) are cited by the Examiner (see Guidelines C-VI, 8.2 and 8.3). Copies of the documents are annexed to the communication and the numbering will be adhered to in the rest of the procedure:
   D8: US-A-5 320 093 (RAEMER DAN [US]) 14 January 1994 (1994-01-14)
   D9: FUJITA TOMOYUKI; ET AL: "Paradoxical rescue from ischemic lung injury by inhaled carbon monoxide driven by derepression of fibrinolysis" NATURE MEDICINE, vol. 7, no. 5, 1 May 2001 (2001-05-01), pages 598-604, XP002283209 NATURE PUBLISHING GROUP, NEW YORK, NY, US; (cited by the applicant)

4. The Examining Division is still of the opinion that the present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 does not involve an inventive step within the meaning of Article 56 EPC.

4.1 Document D2 is considered to be the closest prior art to the subject-matter of claim 1 and discloses an apparatus (20) for administering carbon monoxide to a patient (page 2, lines 31-32), the apparatus comprising a delivering unit (28), a carbon monoxide (page 18, lines 1-2) source (22), a dosing unit (34) for administering carbon monoxide to the patient (page 17, lines 1-16), sensor means

for determining the concentration of carbon monoxide (in the output flow; page 17, lines 18-27), and control means (32) for regulating the dosing unit depending on feedback from the sensor unit (page 18, lines 21-29; page 20, lines 4-19).
Additional remark:
Some of the features listed above are also known from document D9, which additionally discloses a sensor for measuring arterial carboxyhemoglobin (COHb), but lacks to disclose a feedback regulation system.

4.2 The subject-matter of claim 1 therefore differs from this known apparatus in that the sensor determines concentration of carbon monoxide in the blood and the sensor means are selected from the group consisting of: means for measuring the concentration of carboxyhemoglobin (HbCO), means for measuring the concentration of oxyhemoglobin (T-Tb02) in the blood, means for measuring the activity of enzymes in the blood, and means for measuring the composition of the air expired by the patient.
Additional remark:
D2 discloses a sensor measuring concentration of the carbon monoxide (one of 30, 52, 54) in the output flow, i.e. in the gas mixture to be delivered to the patient. From a technical point of view, this CO-sensor is suitable for measuring also the composition (concentration of CO) of (in) the air expired by the patient, depending on the location of the sensor (eg. in a common branch of a Y-piece), however is NOT configured to do so.

Both D2 and the present invention, disclose systems for delivery of CO to a patient, having a feedback regulation. The general difference between those two systems is that **in D2** it is the concentration of CO **in the inhaled gas** set as a feedback parameter and **in the present application**, it is the concentration of CO **in the exhaled gas** set is a feedback parameter.

4.3 The problem to be solved by the present invention may therefore be regarded as how to improve the safety and effectiveness of the administration of the gas to a patient.

4.4 The solution proposed in claim 1 of the present application cannot be considered to involve an inventive step (Articles 52(1) and 56 EPC), for the following reasons:

Inclusion of the patient in a feedback-loop belongs to the general knowledge of a

skilled person. It allows to reduce leakage errors and to reflect physiological differences between different patients, consequently providing for more accurate and effective dosing of the gases. An example of such system is shown in document D8 (see for example column 2, lines 46-68; column 3, lines 8-19; column 5, lines 4-37).

Although only document D2 deals with delivery of carbon monoxide to the patient, but both D2 and D8 deal with the delivery of CO_2 and NO_2, ie. potentially toxic gases, to the patient, where an exact dosing is inevitable in order to minimize risks and provide an optimal effect.

The skilled person would therefore regard it as a normal option to include the feature known from D8 (and his general knowledge) in the apparatus described in document D2 in order to solve the problem posed.

5. The applicant is invited to file an amended set of claims overcoming the above objections.

6. Any new claim 1 will have to be worded in the two-part form incorporating in its pre-characterising portion the features disclosed in the closest prior art D2 (Rule 43(1)(b)EPC).

7. Reference signs should be used throughout the claims (Rule 43(7) EPC).

8. In order to be able to assess the question of inventive step, the applicant is asked to indicate in the response which technical problem is solved by the characterising features of the claim 1 compared to the closest prior art (Rule 42(1)(c) EPC).

9. The description will have to be brought into line with the new claims (Rule 42(1)(c) EPC).

10. The closest prior art (D2) should be indicated in the description (Rule 42(1)(b) EPC).

11. As regards the features contained in the new claims, the applicant is asked to indicate in the response on which passages of original application they are based.

12. The applicant is asked to take into account all of the objections set out above.